

**REMARKS****DISCUSSION OF SPECIFICATION**

In response to the objection of the disclosure because of informalities, on page 4, line 26, "senor" has been replaced with --sensor--. Accordingly, withdrawal of the objection to the disclosure is respectfully requested.

Furthermore, the disclosure has been amended to correct minor typographical errors. In particular, the following amendments have been made: paragraph 82, line 1, "7" has been replaced with --8--; paragraph 85, line 2, "7" has been replaced with --8--; paragraph 87, line 1, "8a" has been replaced with --9a--; paragraph 87, line 3, "8b" has been replaced with --9b--; paragraph 87, line 5, "8a" has been replaced with --9a-- and "8b" has been replaced with --9b--; paragraph 87, line 9, "8b" has been replaced with --9b--; paragraph 88, line 1, "8b" has been replaced with --9b--; paragraph 89, line 1, "8b" has been replaced with --9b--; paragraph 92, line 3, "8c" has been replaced with --9c--; paragraph 92, line 4, "8c," has been replaced with --9c,--; and paragraph 93, line 9, "8c" has been replaced with --9c--. No new matter has been added to the specification. Acceptance of the amendments to the disclosure is respectfully requested.

**DISCUSSION OF CLAIMS**

In the Office Action, claims 5, 6, 9, and 28 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

In the Office Action, claims 1, 2, 5 6, 10, 14-18, 25-29, and 30-33 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,280,409 to Stone et al.

In the Office Action, claims 3 and 4 are rejected under 35 U.S.C. §103(a) as being unpatentable over Stone et al. in view of U.S. Patent No. 5,549,652 to McClure et al.

In the Office Action, claims 7-9 are rejected under 35 U.S.C. §103(a) as being unpatentable over Stone et al. in view of U.S. Patent Publication No. 2002/0138213 to Mault.

In the Office Action, claims 11, 12, 19, and 20 are rejected under 35 U.S.C. §103(a) as being unpatentable over Stone et al. in view of U.S. Patent No. 4,659,077 to Stropkay.

In the Office Action, claims 13 and 24 are rejected under 35 U.S.C. §103(a) as being unpatentable over Stone et al.

In the Office Action, claim 21 is rejected under 35 U.S.C. §103(a) as being unpatentable over Stone et al. in view of Stropkay and further in view of McClure et al..

In the Office Action, claims 22 and 23 are rejected under 35 U.S.C. §103(a) as being unpatentable over Stone et al. in view of Stropkay and further in view of Mault.

In response thereto, claims 1, 3, 15, 18 have been cancelled and claims 4, 5, 7, 10, 11, 13, 14, 16, 17, 19, 24, 25, 27, 29, and 30 have been amended. Accordingly, claims 2, 4-14, 16, 17, and 19-33 are now pending. Following is a discussion of the patentability of each of the pending claims.

#### Preliminary Matter

Claim 3 has been cancelled in response to the objection under 37 CFR 1.75 as being a substantial duplicate of claim 4. Accordingly, withdrawal of the objection of claim 4 is respectfully requested.

#### Independent Claim 4

Claim 4 recites an implantable device for automatically monitoring and reporting patient physical activity. The device comprises at least one implantable sensor operative to provide information related to patient movement and a processor in communication with the at least one implantable sensor. The processor is operative to evaluate the information provided by the at least one sensor, automatically determine when the at least one sensor is indicating patient movement in excess of a threshold

value, and automatically determine a maximum equivalent quantified activity during a determined interval. The sensor comprises an accelerometer, and the device double integrates an acceleration signal from the sensor to determine a distance traveled by the patient so as to automatically determine the maximum equivalent quantified activity during the determined interval.

In accordance with the specification of the present application, natural exercise frequency and intensity can be used as a general diagnostic for the physical and mental condition of a patient. One widely used standard measure of a person's exercise capacity is a six minute walk test. A practical diagnostic drawback with this method of determining the patient's condition is that it can require a stationary treadmill implement. This aspect is disadvantageous as it requires either installation of treadmill equipment at a patient's home for self-testing or a trip to a clinical setting equipped with a treadmill. Further, the six minute walk test as typically administered is not a measure of the natural occurrence of a patient's exercise, but rather a measure taken under artificial conditions. Patient surveys can be administered to solicit information about their normal, natural activities, however, as is known in the art, self-surveys can be inaccurate. Thus, it would be desirable to have a convenient, unobtrusive method of determining a patient's capacity for and natural frequency of taxing exercise. It would be advantageous to be able to gather the information in an invisible manner from the patient's perspective so as to reduce the patient's conscious awareness of the data gathering and thus reducing artificial impact on their natural tendencies. It would also be beneficial to automatically evaluate the patient's natural exercise activity in an equivalent to a clinical six minute walk test to allow comparison to a standard measure. What is recited in claim 4 of the present application satisfies these needs.

It is apparently conceded that the Stone et al. reference does not disclose or suggest a device double integrating an acceleration signal in order to determine a distance traveled by the patient so as to automatically determine the maximum equivalent quantified activity during the determined interval. For this reason, it appears the Examiner has introduced the McClure et al. reference. The McClure et al.

reference does not disclose or suggest double integrating an acceleration signal in order to determine a distance traveled by the patient. In accordance with the McClure et al. reference, cardiac wall motion is determined by double integrating cardiac wall motion accelerations.

Furthermore, it is respectfully submitted that any rejection of claim 4 based on a combination of these references, however, would be improper. "Before the PTO may combine the disclosures of two or more prior art references in order to establish prima facie obviousness, there must be some suggestion for doing so." In re Jones, 21 USPQ2d 1941 (Fed. Cir. 1992). As there is no suggestion in the references for the proposed combinations, any rejection of the pending claims would fail to present a prima facie case of obviousness. In particular, both references (Stone et al. and McClure et al) do not address the concept of having a convenient, unobtrusive method of determining a patient's capacity for and natural frequency of taxing exercise, gathering information in an invisible manner from the patient's perspective so as to reduce the patient's conscious awareness of the data gathering and thus reducing artificial impact on their natural tendencies, and automatically evaluating the patient's natural exercise activity in an equivalent to a clinical six minute walk test to allow comparison to a standard measure.

The Stropkay reference is cited in combination with the Stone et al. reference because it allegedly discloses an exercise device that determines an equivalent distance traveled by a user. Nowhere does the Stropkay reference disclose or suggest a device double integrating an acceleration signal in order to determine a distance traveled by the patient so as to automatically determine the maximum equivalent quantified activity during the determined interval.

The Mault reference is cited in combination with the Stone et al. and Stropkay references because it allegedly discloses use of a GPS position sensor. Nowhere does the Mault reference disclose or suggest a device double integrating an acceleration signal in order to determine a distance traveled by the patient so as to

automatically determine the maximum equivalent quantified activity during the determined interval.

Accordingly, it is respectfully submitted that claim 4 is in condition for allowance.

Independent Claim 11

Claim 11 recites an implantable device for automatically monitoring and reporting patient physical activity. The device comprises at least one implantable sensor operative to provide information related to patient movement and a processor in communication with the at least one implantable sensor. The processor is operative to evaluate the information provided by the at least one sensor, automatically determine when the at least one sensor is indicating patient movement in excess of a threshold value, and automatically determine a maximum equivalent quantified activity during a determined interval. The determining the maximum equivalent quantified activity during the determined interval comprises determining a maximum equivalent distance walked.

It is apparently conceded that the Stone et al. reference does not disclose or suggest a maximum equivalent quantified activity during a determined period comprising determining a maximum equivalent distance walked. For this reason, it appears the Examiner has introduced the Stropkay reference. It is respectfully submitted that any rejection of claim 11 based on a combination of these references, however, would be improper. "Before the PTO may combine the disclosures of two or more prior art references in order to establish prima facie obviousness, there must be some suggestion for doing so." In re Jones, 21 USPQ2d 1941 (Fed. Cir. 1992). As there is no suggestion in the references for the proposed combinations, any rejection of the pending claims would fail to present a prima facie case of obviousness. In particular, both references (Stone et al. and Stropkay) do not address the concept of having a convenient, unobtrusive method of determining a patient's capacity for and natural frequency of taxing exercise, gathering information in an invisible manner from

the patient's perspective so as to reduce the patient's conscious awareness of the data gathering and thus reducing artificial impact on their natural tendencies, and automatically evaluating the patient's natural exercise activity in an equivalent to a clinical six minute walk test to allow comparison to a standard measure.

The McClure et al. reference is cited in combination with the Stone et al. and Stropkay references because it allegedly discloses double integrating an acceleration signal in order to determine displacement. Nowhere does the McClure et al. reference disclose or suggest a maximum equivalent quantified activity during a determined period comprising determining a maximum equivalent distance walked.

The Mault reference is cited in combination with the Stone et al. and Stropkay references because it allegedly discloses use of a GPS position sensor. Nowhere does the Mault reference disclose or suggest a maximum equivalent quantified activity during a determined period comprising determining a maximum equivalent distance walked.

Accordingly, it is respectfully submitted that claim 11 is in condition for allowance.

#### Dependent Claims 2, 5-10 and 12-14

Claims 2, 5-10, and 12-14 depend from claim 11 and are similarly patentable. Accordingly, it is respectfully submitted that these claims are in condition for allowance.

#### Independent Claim 19

For at least the same reasons discussed previously with regards to claim 11, it is respectfully submitted that claim 19 is in condition for allowance.

Dependent Claims 16, 17, and 20-29

Claims 16, 17, and 20-29 depend from claim 19 and are similarly patentable. Accordingly, it is respectfully submitted that these claims are in condition for allowance.

Independent Claim 30

For at least the same reasons discussed previously with regards to claim 11, it is respectfully submitted that claim 30 is in condition for allowance.

Dependent Claims 31-33

Claims 31-33 depend from claim 30 and are similarly patentable. Accordingly, it is respectfully submitted that these claims are in condition for allowance.

**CONCLUSION**

In light of the above amendments and remarks, it is respectfully submitted that the application is in condition for allowance, and an early notice of allowance is requested.

Respectfully submitted,

8/2/06

Date



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